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REMARKS

Claims 9 and 38-44 are pending and under examination in the subject application. Applicants have not added, canceled or amended any claims herein. Accordingly, upon entry of this Amendment, claims 9 and 38-44 will still be pending and under examination.

Species Election

In the July 18, 2005 Office Action, the Examiner states that applicants are required to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 9, 43 and 44 are generic. The Examiner alleges that the pending claims are directed to the following patentably distinct species:

- I. Pharmaceutical compositions comprising an inactive Christmas factor, classified in Class 514, Subclass 8;
- II. Pharmaceutical compositions comprising a carboxylated Christmas factor, classified in Class 514, Subclass 8;
- III. Pharmaceutical compositions comprising a des- γ -carboxyl Factor IX, classified in Class 424, Subclass 94.64;
- IV. Pharmaceutical compositions comprising Factor IX lacking a calcium-dependent membrane binding function, classified in Class 424, Subclass 94.64;

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- V. Pharmaceutical compositions comprising Factor IX Bm Kiryu, classified in Class 424, Subclass 94.64;
- VI. Pharmaceutical compositions comprising glycosylated Factor IXa, classified in Class 424, Subclass 94.64;
- VII. Pharmaceutical compositions comprising Factor IXa having β -hydroxylation of aspartic acid, classified in Class 424, Subclass 94.64;
- VIII. Pharmaceutical compositions comprising Factor IXa having γ -carboxylation of glutamic acid, classified in Class 424, Subclass 94.64;
- IX. Pharmaceutical compositions comprising Factor IXa having propeptide cleavage, classified in Class 424, Subclass 94.64;
- X. Pharmaceutical compositions comprising an inactive mutein form of Factor IXa having a Ser185 to Ala substitution, classified in Class 424, Subclass 94.64;
- XI. Pharmaceutical compositions comprising an inactive mutein form of Factor IXa including only residues 1-47, classified in Class 424, Subclass 94.64;
- XII. Pharmaceutical compositions comprising an inactive mutein form of Factor IXa having a Val313 to Asp substitution in the catalytic domain of Factor IX, classified in Class

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424, Subclass 94.64;

- XIII. Pharmaceutical compositions comprising an inactive mutein form of Factor IXa having a Gly311 to Glu substitution in the catalytic domain of Factor IX, classified in Class 424, Subclass 94.64;
- XIV. Pharmaceutical compositions comprising an inactive mutein form of Factor IXa having a Gly311 to Glu substitution in the catalytic domain of Factor IX, classified in Class 424, Subclass 94.64;
- XV. Pharmaceutical compositions comprising an inactive mutein form of Factor IXa having a Gly311 to Arg318 deletion, classified in Class 424, Subclass 94.64;
- XVI. Pharmaceutical compositions comprising an inactive mutein form of Factor IXa having an amino acid substitution at His221, classified in Class 424, Subclass 94.64;
- XVII. Pharmaceutical compositions comprising an inactive mutein form of Factor IXa having an amino acid substitution at Asp269, classified in Class 424, Subclass 94.64;
- XVIII. Pharmaceutical compositions comprising an inactive mutein form of Factor IXa having an amino acid substitution at Ser365, classified in Class 424, Subclass 94.64;
- XIX. Pharmaceutical compositions comprising an inactive mutein form of Factor IXa having an amino acid substitution at

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His41 in the heavy chain of Factor IXa, classified in Class 424, Subclass 94.64;

XX. Pharmaceutical compositions comprising an inactive mutein form of Factor IXa having an amino acid substitution at Asp89 in the heavy chain of Factor IXa, classified in Class 424, Subclass 94.64;

XXI. Pharmaceutical compositions comprising an inactive mutein form of Factor IXa having an amino acid substitution at Ser185 in the heavy chain of Factor IXa, classified in Class 424, Subclass 146.1;

XXII. Pharmaceutical compositions comprising an anti-Factor IX antibody or fragment thereof, classified in Class 424, Subclass 146.1;

XXIII. Pharmaceutical compositions comprising a small organic molecule, classified in Class 514, Subclass 1; and

XXIV. Pharmaceutical compositions comprising a peptidomimetic, classified in Class 514, Subclass 1.

In response, applicants hereby elect the species of Group 18, corresponding to pharmaceutical compositions comprising an inactive mutein form of Factor IXa having an amino acid substitution at Ser365, with traverse, for prosecution at this time.

However, applicants maintain that examining the remaining groups would not place a burden on the Examiner, and that thus, the

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remaining groups should be examined together. In particular, applicants maintain this position regarding Groups 10 and 21. Specifically, the designation "Ser365" in Factor IXa, as provided in Groups 10 and 18, refers to the same serine residue as the designation "Ser185" in the heavy chain of Factor IXa, as provided in Group 21. In support of their position, applicants direct the Examiner's attention to page 8, lines 19-24, which states, in relevant part, that (i) Ser365 is one of three amino acids located on the heavy chain of Factor IXa principally responsible for catalytic activity; and (ii) if the amino acids of the heavy chain of Factor IXa were numbered 1 to 235, Ser365 would be Ser185. Accordingly, applicants maintain that (i) Groups 18 and 21 provide the same pharmaceutical composition, and (ii) the pharmaceutical composition of Group 10 comprising an inactive mutein form of Factor IXa having a Ser185 to Ala substitution, is simply a subset of the pharmaceutical compositions of Groups 18 and 21 comprising an inactive mutein form of Factor IXa having an amino acid substitution at Ser185 of the heavy chain of Factor IXa. Accordingly, examining the species of the remaining Groups together, especially Groups 10 and 21, would not constitute an undue burden for the Examiner, once the species of Group 18 has been searched and examined.

The July 18, 2005 Office Action also requires a listing of all claims readable on the elected species. In response, applicants note that each of claims 9 and 38-44 reads upon the elected species.

In addition, applicant notes that upon the allowance of a generic claim, consideration of claims to additional species which are

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written in dependent form are to be considered.

Sequence Rules

In the July 18, 2005 Office Action, the Examiner indicated that the Sequence Listing submitted by the applicants on April 21, 2005 was not approved by the STIC.

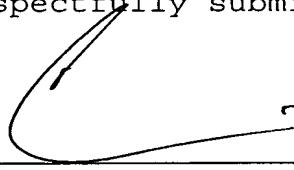
In response, applicants annex hereto a paper copy of the amended Sequence Listing as Exhibit A, a Statement in Accordance with 37 C.F.R. §1.821(f) as Exhibit B, and a C.R.F. of the Sequence Listing. Applicants have also amended the specification to reflect the SEQ. ID. NOs.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

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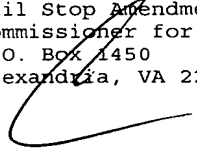
No fee is deemed necessary in connection with the filing of this Amendment. If any such fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



John P. White
Registration No. 28,678
Alan J. Morrison
Registration No. 37,399
Attorneys for Applicants
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, New York 10036
Tel. No. (212) 278-0400

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Alan J. Morrison

8/18/01
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Registration No. 37,399